

Notice of Allowability

Application No.

10/069,145

Applicant(s)

AHOLA ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 02 November 2005.
2. ☒ The allowed claim(s) is/are 8, 10-12 and 15-17.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7. ☒ The Drawings filed 02/22/02 are accepted by the Examiner.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action, Amendment to claims & specification and Applicant's Arguments/Remarks, all filed 11/02/05 is acknowledged.

Claims 8, 10-12 and 15-17 are pending in this action. Claims 8 and 12 have been amended. New claim 17 has been added. Claims 1-7, 9, 13 and 14 have been cancelled. Claims 8, 10-12 and 15-17 are allowed.

EXAMINER'S AMENDMENT

The application has been amended as follows:

In the Specification:

On page 1, between the title and line 4, after the words 'English language', the phrase "**This application claims priority to foreign Finland Application No. 19991806 filed August 25, 1999**" has been added.

Allowable Subject Matter

Claims 8, 10-12 and 15-17 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Zang *et al.* – U.S. Pat. No. 5,858,280; Pinchuk *et al.* – U.S. Pat. No. 5,804,318; Kuncova *et al.* – Collect. Czech. Chem.

Comm.) does not disclose nor fairly suggest or teach a biodegradable silica xerogel composition that contains heparin or a related biologically active acidic polysaccharide. The prior art further does not disclose nor teach or suggest a silica xerogel derived from tetraethoxysilane, wherein part of the tetraethoxysilane is replaced by an alkylsubstituted alkoxy silane, as instantly claimed. There is no remote teaching or suggestion of heparin controllably released from a sol-gel derived silica xerogel derived from tetraethoxysilane. Contrastingly, the prior art (Pinchuk *et al.* '280) teaches a transparent methyl-modified silica gel and the prior art (Pinchuk *et al.* '318) teaches a surface coating comprising *non*-silica hydrogel containing pendant primary and tertiary amine groups. The Kuncova *et al.* reference is directed to the immobilization of lipase into an organic-inorganic matrix, and thus, also fails to disclose or suggest a biodegradable composition for controlled release of heparin (or a related biologically active acidic polysaccharide) from a carrier. Moreover, the Kuncova *et al.* reference fails to disclose the partial replacement of tetraethoxysilane with an alkylsubstituted alkoxy silane.

The instant invention demonstrates an improvement over prior art formulations because it provides for the controlled release of heparin or a related biologically active acidic polysaccharide, whereby the composition can be used for systemic or local treatment of medical or surgical thrombosis. The instant invention also provides for convenient administration routes of heparin, especially for long-acting, controlled release dosage forms of heparin.

Hence, in view of the lack of teachings of a composition containing heparin or a related biologically active acidic polysaccharide, controllably released from a sol-gel derived silica xerogel derived from tetraethoxysilane as instantly claimed and the improvements demonstrated

by the present invention, the instant invention is rendered non-obvious and patentable over the cited art of record.

Applicant's amendment filed 11/02/05 sufficiently overcomes all objections and rejections recited in the Non-Final Office Action dated 09/19/05.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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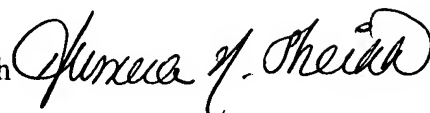
system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

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January 23, 2006



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